

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KLAUS NEUER,
MONIKA PETSZULAT and HATTO WALCH

Appeal No. 2003-1422
Application 09/738,212

ON BRIEF

Before WILLIAM SMITH, GRIMES, and POTEATE, **Administrative Patent Judges.**

POTEATE, **Administrative Patent Judge.**

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 21-30 and 33. Claims 31 and 32 are also pending, but have been withdrawn from consideration as directed to a non-elected invention. Claims 21 and 33 are representative of the subject matter on appeal and are reproduced below:

21. A hard gelatin capsule comprising
(a) a cyclosporin as active ingredient,
(b) a polyethoxylated saturated hydroxy-fatty acid, and
(c) a C₂-C₃ alcohol having one or two hydroxy groups.
33. A hard gelatin capsule of claim 21 further comprising
(d) mono-, di- and/or triesters of fatty acids, and optionally
(e) ricinoleic acid glyceride(s) together with smaller proportions of multiply unsaturated fatty acid glycerides or castor oil
as a unit dosage form.

The references relied upon by the examiner are:

| | | |
|----------------------|-----------|----------------|
| Orbán et al. (Orbán) | 5,047,396 | Sept. 10, 1991 |
| Hauer et al. (Hauer) | 5,342,625 | Aug. 30, 1994 |

GROUND OF REJECTION

1. Claim 33 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

We affirm.

2. Claims 21-30 and 33 stand rejected under 35 U.S.C. § 103 as unpatentable over Orbán in view of Hauer.

We reverse.

3. Claims 21-30 and 33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/690,400.

We reverse.

4. Claims 21-30 and 33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 09/605,512.

We vacate.

5. Claims 21-30 and 33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15, 17, 19, 24, 26 and 28 of copending Application No. 09/547,802.

We affirm.

BACKGROUND

The invention relates to a hard gelatin capsule comprising cyclosporin as the active ingredient, a poly-ethoxylated saturated hydroxy-fatty acid and a C₂-C₃ alcohol. Claim 21. Cyclosporins possess anti-inflammatory and anti-parasitic activity and are used for a variety of applications which include the treatment of inflammatory disorders and various auto-immune diseases. Specification, page 1.

Cyclosporins have a strongly hydrophobic character and are difficult to process with the usual pharmaceutical excipients

to form preparations having sufficient bioavailability. *Id.*, page 2. It is known to administer cyclosporin intravenously. *Id.*, page 3. However, a disadvantage of intravenous preparations is that they must be administered in clinics by trained personnel. *Id.* Oral preparations, though more easily administered, suffer from the drawback of low and variable bioavailability. *Id.*, page 4. See Hauer, column 3, lines 57-61. According to appellants, the claimed oral cyclosporin preparation provides comparable bioavailability to intravenously administrable preparations. Specification, page 7.

DISCUSSION

1. *Rejection of claim 33 under 35 U.S.C. § 112, second paragraph, as indefinite*

According to the examiner, claim 33 is vague and indefinite because it is unclear what appellants are claiming for component (e). Examiner's Answer, Paper No. 14, mailed January 15, 2003, page 3. In particular, the examiner maintains that it is unclear as to whether appellants are claiming a combination of ricinoleic acid glycerides and multiply unsaturated fatty acid glycerides, or castor oil, or whether appellants are claiming a mixture of ricinoleic acid glycerides

with multiply unsaturated fatty acid glycerides, or a mixture of ricinoleic acid glycerides with castor oil. While appellants attempt to explain what is intended by this language (see Appeal Brief, Paper No. 13, received October 16, 2002, page 2), we are in agreement with the examiner that the claim language is indefinite. In fact, even upon reading appellants' explanation as to what is intended by this language, we are still unclear as to what is being claimed. We are further in agreement with the examiner that the language "smaller proportions of multiply unsaturated fatty acid glycerides" is indefinite as it is unclear what the basis for comparison is. See Examiner's Answer, page 3.

**2. Rejection of claims 21-30 and 33 under 35 U.S.C.
§ 103 as unpatentable over Orbán in view of Hauer**

It is the examiner's position that Orbán discloses the cyclosporin composition of claim 21, but fails to teach that the composition may be provided in a hard gelatin capsule. See Examiner's Answer, page 8. The examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of the invention to have prepared Orbán's composition in a hard gelatin capsule in view of the teachings of Hauer. *Id.*, page 5. In particular, the examiner notes that Hauer is directed to pharmaceutical compositions comprising cyclosporins which include

an alcohol and may contain a single surfactant, such as polyoxyethylene stearic acid ester. *Id.*, page 4. Hauer's composition may be provided in hard or soft gelatin capsules.

Id.

Appellants argue that Orbán's disclosure is limited to a cyclosporin containing composition for intravenous administration. Appeal Brief, page 3.¹ According to appellants, "[t]here is no teaching or suggestion that this composition may also be advantageous with respect to stability and bioavailability in medicaments for oral administration." *Id.* While appellants do not dispute the examiner's finding that Hauer discloses a cyclosporin-containing composition in a hard gelatin capsule, they maintain that there would have been no motivation to have combined the teachings of Orbán and Hauer since Orbán fails to disclose or suggest that his composition may also be used for oral administration. Appeal Brief, page 3.

"[T]he question under 35 U.S.C. § 103 is not merely what the references expressly teach, but what they would have

¹Appellants also note that one of the differences between Hauer's composition and that of the claimed invention is that the present invention requires a polyethoxylated saturated hydroxy-fatty acid component which is not taught by Hauer. *Id.*

suggested to one of ordinary skill in the art at the time the invention was made." *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976). In order to establish a *prima facie* case of obviousness, the examiner must identify a suggestion or motivation to modify the teachings of the cited references to achieve the claimed invention. *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). The suggestion or motivation to modify a reference may be implicit from the prior art as a whole rather than expressly stated. *Id.* However, regardless of whether the examiner relies on an express or implicit showing, he must provide reasons for finding a limitation to be taught or suggested in the reference. *Id.*

We are in agreement with appellants, that the examiner has failed to satisfy his burden of identifying a suggestion or motivation to modify the teaching of Orbán in view of Hauer to achieve the claimed invention. In support of his proposed combination, the examiner states that

[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '396 in a hard gelatin capsule as taught by US '625 with the reasonable expectation of obtaining a cyclosporin composition that provides convenient oral administration and

improved bioavailability. [Examiner's Answer,
page 5.]

However, the examiner has failed to identify any support in the references for this conclusion. In reviewing Orbán, we are in agreement with appellants that the reference is clearly limited to an intravenous pharmaceutical composition. See, e.g., Orbán, column 2, lines 9-14 ("Therefore our aim was to work out an intravenous pharmaceutical composition comprising cyclosporin as active ingredient which is more tolerable than the known intravenous formations, i.e., its anaphylactic-hypersensibilizing effect is smaller than that of the known formulation."). By contrast, Hauer is strictly limited to a cyclosporin containing composition which is suitable for use in topical formulations and, in particular, oral dosage forms. See Abstract.

Having found that the examiner has failed to establish a **prima facie** case of obviousness, the rejection is reversed.

**3. Provisional rejection of claims 21-30 and 33
under the judicially created doctrine of obvious-
type double patenting as being unpatentable
over claims 1-30 of copending Application
No. 09/690,400**

Application No. 09/690,400 issued as U.S. Patent
No. 6,258,808 on July 10, 2001. We have reviewed the claims of
the issued patent and have concluded that they are not directed
to the same invention claimed in present claims 21-30 and 33, and
do not render obvious claims 21-30 and 33.

The rejection is reversed.

**4. Provisional rejection of claims 21-30 and 33
under the judicially created doctrine of obvious-
type double patenting as being unpatentable
over claims 1 and 2 of copending Application
No. 09/605,512**

Application No. 09/605,512 was abandoned on
March 26, 2002. Accordingly, we vacate this ground of rejection.

**5. Provisional rejection of claims 21-30 and 33
under the judicially created doctrine of obvious-
type double patenting as being unpatentable
over claims 1-3, 5-8, 15, 17, 19, 24, 26
and 28 of copending Application No. 09/547,802**

Appellants fail to present arguments traversing this
ground of rejection. See Appeal Brief, page 4. Accordingly,
the rejection is affirmed.

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In sum, we affirm the rejection of claim 33 under 35 U.S.C. § 112, second paragraph, and affirm the provisional obviousness-type double patenting rejection of claims 21-30 and 33 based on copending Application No. 09/547,802. We reverse the provisional obviousness-type double patenting rejection based on Application No. 09/690,400, now patented. We vacate the provisional rejection of claims 21-30 and 33 under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1 and 2 of Application No. 09/650,512, now abandoned. We reverse the rejection of claims 21-30 and 33 under 35 U.S.C. § 103 as unpatentable over Orbán in view of Hauer.

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TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
WILLIAM F. SMITH

Administrative Patent Judge

Eric Gini

ERIC GRIMES

Administrative Patent Judge

Linda R. Pteale

LINDA R. POTEATE

Administrative Patent Judge

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LRP:psb

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